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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/598,327 | 08/24/2006 | **Olivier Gerard** | FR040029US | 2707 |

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PHILIPS INTELLECTUAL PROPERTY & STANDARDS
P.O. BOX 3001
Briarcliff Manor, NY 10510-8001

| EXAMINER | |
|---|---|
| GUPTA, VANI | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 3768 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
| 12/29/2009 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/598,327 | GERARD ET AL. | |
| | Examiner | Art Unit | |
| | VANI GUPTA | 3768 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *29 September 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Terminal Disclaimer*

**1.** The terminal disclaimer filed on 10/28/09 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of any patent granted on Application number 10/596,434 has been reviewed and is accepted. The terminal disclaimer has been recorded.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

***Inventorship***

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**1.** ***Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kusch (US 2002/0018588 A1) in view of Gilboa et al. (US 6,996,430 B1).***

**Regarding Claim 1,** Kusch discloses a medical imaging system ***(FIGURE)*** comprising

a. an X-ray acquisition means ***(C-arm x-ray apparatus; 1)*** capable of acquiring a two-dimensional X-ray image comprising a projection of said medical instrument in accordance with a geometry of said X-ray acquisition means ([0023 - 0025];

b. an ultrasound acquisition means ***(ultrasound device; 2)*** capable of acquiring a three-dimensional ultrasound data set of medical instrument using an ultrasound probe ***(ultrasound scanner; 24)*** (pgs. [0013], [0022 – 0026]);

c. a means for localizing ***(reference elements of navigation system; 6 and 7)*** said ultrasound probe within a referential of the X-ray acquisition means (pg. [0027 - 0028]);

d. a means for providing a first ultrasound localization of said medical instrument within a referential of said ultrasound acquisition means (***Figure, #7 and 8***; and pg. [0030]). Reference (***8***) capable of being coupled to a "subject" such as a medical device (pg. [0022], second to last sentence);

e. means for converting said first ultrasound localization within said referential of the ultrasound acquisition means into a first X-ray localization within said referential of the X-ray acquisition means, using said localization of the ultrasound probe (pg. [0028]);

f. means for providing a second X-ray localization of said projection of the medical instrument in a referential of said two-dimensional X-ray image (***Figure, #6 and 8***; and pg. [0030]; and rejection of Claim 1(d));

g. means for mapping said three-dimensional ultrasound data set with said two-dimensional X-ray image in accordance with a transformation, which minimizes a distance between a projection of said first X-ray localization on said two-dimensional X-

Ray image in accordance with said geometry of the X-ray acquisition means and said second X-ray localization; and means for generating and displaying a bi-modal representation of said medical instrument in which said two-dimensional X-ray image and said mapped three-dimensional ultrasound data set are combined (Figure, 19, 21, 25, 26; and pg. [0029 – 0034]; wherein "calibration" minimizes the distance, or corrects measurements of positions of objects of interest).

However, Kusch differs from claim 1 in that Kusch does not specifically suggest that the "subject" to which reference (8) may be coupled to is a medical instrument to be guided in a patient body.

Nonetheless, Gilboa et al. teaches a "treatment-applying probe" (***fig. 1, 170;*** and col. 7, lines 51 – 60), which may be used by a dual-modality imaging system, comprising ultrasound and tomography imaging capabilities. The probe may be navigated within the body with assistance of the imaging devices (***figs. 1 and 3***; and col. 4, lines 1 – 25).

Accordingly, it would have been prima facie obvious to modify the dual-medical imaging system of Kusch to include the medical device of Gilboa et al., because an "increasing number of medical procedures are performed by navigating a probe within a body," which is accomplished by assistance of fluoroscopic (tomographic) and ultrasound imaging (col. 1, lines 55 – 65). Gilboa et al.'s probe is designed with this in mind (col. 8, line 49 – col. 9, line 20).

***Regarding Claim 2***, Kusch discloses that means for providing a first ultrasound localization and said means for providing a second X-Ray localization of said medical

instrument comprise detection means for detecting localization features of said medical instrument (see rejection of Claim 1(d) and (3).

***Regarding Claims 3 – 6 and 8***, the limitations refer to features that do not further limit the structure of the present invention. Additionally, Kusch or Kusch in view of Gilboa et al. is capable of performing the functionality of Claim 1, while keeping the present features in mind: (Gilboa et al.: col. 8, lines 29 – 30 and col. 9, lines 41 – 44).

***Furthermore, with respect to Claim 5***, Applicant should note that means for detecting said localization features that comprise a plurality of landmarks of said medical instrument is an obvious variant of claims 2 and 3, as it is known in the art to perform the same function multiple times and mere duplication of the essential working parts of a device involves only routine skill in the art. See *in re* St. Regis Paper Co. vs. Bemis Co., 193 USPQ 3, 11 (7th Cir. 1977). ***The same applies to*** transformation comprises a translation and three rotations of ***Claim 6***.

***Regarding claims 7 and 9***, the limitations refer to features that do not further limit the structure of the present invention, but rather refer to intended use of non-structural (or functional) features of the present invention. Furthermore, Kusch or Kusch in view of Gilboa et al. is not structurally limited from accomplishing the objectives of these claims (see Gilboa et al. for further details —preferred line of sight (PLOS), col. 9 , line 45 – col. 10, line 56).

***Regarding Claim 10***, for a method of guiding a medical instrument in a patient body, comprising the steps of:

a. acquiring a two-dimensional X-ray image using an X-ray acquisition system, said two- dimensional X-ray image comprising a projection of said medical instrument in

accordance with a geometry of said X-ray acquisition system; acquiring a three-dimensional ultrasound data set of said medical instrument using said ultrasound probe; and localizing said ultrasound probe in a referential of said X-ray acquisition system (see Kusch and rejection of Claim 1);

b. providing a first localization of said medical instrument within a referential of said 3D ultrasound data set (see Kusch in view of Gilbon et al. and rejection of Claim 1);

c. converting said first localization within said referential of the 3D ultrasound data set into a first X-Ray localization within said referential of the X-ray acquisition system; and providing a second localization of said projection of the medical instrument in a referential of the two-dimensional X-Ray image (see Kusch and rejection of Claim 1);

d. mapping said three-dimensional ultrasound data set with said two-dimensional X-ray image in accordance with a transformation, which minimizes a distance between a projection of said first X-Ray localization on said two-dimensional X-Ray image in accordance with said geometry of the X-Ray acquisition means and said second localization (see Kusch: pg. [0030 - 0032] wherein "calibration" minimizes the distance, or corrects measurements of positions of objects of interest).

e. generating and displaying a bimodal representation of said medical instrument in which both 2D X-ray image and said mapped 3D ultrasound data are combined (Kusch – combined images with reference (8) registered with image – pgs. [0030] and [0034]; and Gilboa et al., wherein reference is coupled to medical device and imaging of device itself - col. 7, lines 51 – 52).

***Response to Arguments***

**1.** ***Applicant's arguments filed September 29, 2009 have been fully considered but are not persuasive.***

Applicant argues that cited prior art does not suggest "mapping transformation three-dimensional ultrasound data sets and two-dimensional X-ray images."

Examiner respectfully disagrees and directs Applicant to Kusch, paragraph [0030], where Kusch discusses mapping the two types of images to produce "correction allocation of bones structures and soft tissue," which suggests minimizing a distance D between projections of the x-ray localizations.

Applicant also argues that cited prior art does not suggest "localizing an ultrasound probe localizing an ultrasound probe to the coordinate reference system of an x-ray acquisition system. Examiner respectfully disagrees. First of all, the claims claim "means for localizing the probe with a *referential of the X-ray acquisition means.* Kusch does that as explained in paragraphs [0027 - 0028]. Second of all, the disclosure does not present the term "coordinate system of x-ray." Even if it did, Applicant should note that for features not recited in the rejected claim(s): although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

With respect to the Gilboa et al.'s locating system ***(130)***, locating system works in conjunction with fluoroscope ***(110)*** (col. 1, ll. 56 – 57; and col. 9, ll. 7 – 11), and therefore is part of the coordinate system of the x-ray acquisition system. Kusch's optical navigation system (3) includes elements (6,7,8) that are "arranged on the x-ray apparatus" and "allows postion of the x-

ray system to be identified" and "interprets images of the x-ray system to be provided with reference element ***(6)*** (para. [0027 - 0028]); and therefore is part of the coordinate system of the x-ray acquisition system.

Applicant also argues that Kusch in view of Gilboa does not suggest showing an image of the probe, but rather depicts a graphical representation of the probe. Examiner disagrees and directs applicant to Kusch, who states that an object such a medical device (reference elements 6 – 8) can be shown in an image. See paragraphs ([0022 - 0025]).

In light of the foregoing rejection and responses, it is respectfully submitted that this application is NOT in condition for allowance.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Communication***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VANI GUPTA whose telephone number is (571)270-5042. The examiner can normally be reached on Monday - Friday (8:30 am - 5:30 pm; EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/V. G./
Examiner, Art Unit 3768

/Long V Le/
Supervisory Patent Examiner, Art Unit 3768